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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,216	06/29/2005	Mark Tawa	TP15013USPTC6	4554

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
07/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,216	TAWA ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-74* is/are pending in the application.

4a) Of the above claim(s) *69-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments over the 35 USC 103 rejection over Arora et al. in view of Carter have been fully considered. In particular, Applicants argue that Arora is concerned with topical application of COX-2 inhibitors and not oral administration as now claimed in claim 46. Therefore, the combination of Carter, which teaches salts of celecoxib, would not read on the invention because it would still result in a topical formulation.

The above arguments are considered persuasive and the rejections are withdrawn. Accordingly, new rejections are being applied below. As these rejections were not previously applied, this Office Action is being made a non-final.

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46-68 rejected under 35 U.S.C. 102(e) as being anticipated by Remenar et al. (US PgPub 2006/0052432)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Remenar et al. teaches pharmaceutical compositions that include an API having low aqueous solubility that is less than or equal to 10 mg/mL (paragraph 0172). It is taught that the API is formulated with a precipitation retardant (paragraph 0174). The precipitation retardants, such as poloxamers, have an interfacial tension less than 10 dyne/cm and a surface tension less than 42 dyne/cm (paragraph 0174). Also included in the compositions are precipitation retardant enhancers which include hydroxypropyl cellulose (paragraph 0182). In preferred embodiments, the compositions comprise a salt of celecoxib that is an alkali metal salt including sodium, potassium and lithium (paragraphs 0199 and 0200). Example 15 teaches a formulation with celecoxib sodium salt hydrate and a poloxamer and hydroxypropyl cellulose (if added). The compositions are formulated for oral administration (paragraph 0076).

The claim limitations in claims 52-54 that recite crystallization or precipitation is retarded for a specific amount of time is considered a property of the composition. Because the prior art anticipates the composition, it will inherently have the same properties. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claims limitations in claims 60-62, 66-68 that recite the bioavailability of the composition is considered a property of the composition. Because the prior art anticipates the composition, it will inherently have the same properties. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claim limitations in claims 63-65 that recited the Cmax of the composition is considered a property of the composition. Because the prior art anticipates the composition, it will inherently have the same properties. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-68 rejected under 35 U.S.C. 103(a) as being unpatentable over Tawa et al. (US PgPub 2007/0015841) in view of Remenar (US PgPub 2006/0052432).

Tawa et al. teach a salt form of celecoxib that is significantly more stable in water than neutral celecoxib, in addition to a binding agent that includes poloxamers (attention is drawn to Poloxamer 188 and Poloxamer 237; paragraphs 0116-0117, 130). The salt forms of celecoxib include metal salts such as sodium salt (paragraph 0068). The

compositions are formulated as oral formulations (paragraph 0068). The compositions optionally comprise a binding agent such as hydroxypropylcellulose (paragraph 0115).

Tawa et al. does not teach that the surfactant exhibits an interfacial tension of less than about 10 dyne/cm or a surface tension of less than about 42 dyne/cm.

Remenar teaches that Poloxamer 188 and Poloxamer 237 are poloxamers that have a surface tension of less than 42 dyne/cm and an interfacial tension of less than 10 dyne/cm.

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Tawa et al. which teaches compositions comprised of a salt form of celecoxib mixed with a poloxamer, with the teachings of Remenar which teaches that Poloxamer 188 and Poloxamer 237 (which are used in the invention of Tawa). One would be motivated to use the teachings of Remenar to verify the interfacial tension and surface tension of the poloxamer which will help solubilize the celecoxib salt.

The claim limitations in claims 52-54 that recite crystallization or precipitation is retarded for a specific amount of time is considered a property of the composition. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claims limitations in claims 60-62, 66-68 that recite the bioavailability of the composition is considered a property of the composition. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The claim limitations in claims 63-65 that recited the Cmax of the composition is considered a property of the composition. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627